SENT BY: VAN DYKE LAW;

Docket No.: UF-10488R Serial No.: 10/005,374

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## In the claims:

- 1. (original) Biocompatible particles for delivery of a vaccine to the pulmonary system comprising an immunizing agent; wherein the particles have a tap density less than 0.4 g/ml and at least 90% of the particles have geometric dimensions between about 5 µm and about 30 μm.
- 2. (original) The particles of claim 1 wherein the immunizing agent is selected from the group consisting of a live attenuated virus or bacterial vaccine, a recombinant virus or bacterial vaccine encoding an immunizing antigen or a combination of antigens against which elicitation of an immune response is desired, and an inactivated virus or bacterial vaccine.
- 3. (currently amended) The particles of claim 1 combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 .mu.m um to about 100 .mu.m μm.
- 4. (original) The particles of claim 1 combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.
- 5. (currently amended) The particles of claim 1 wherein at least 90% of the particles have a mass mean diameter between about 5 .mu.m µm and about 15 .mu.m µm.
- 6. (currently amended) The particles of claim 1 wherein at least 90% of the particles have a mean diameter between about 9 .mu.m μm and about 11 .mu.m μm.
- 7. (currently amended) The particles of claim 1 wherein at least 50% of the particles have a tap

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density of less than 0.1 g/cm.sup.3 g/cm3.

- 8. (original) The particles of claim 1 wherein the particles further comprise a polymeric material.
- 9. (original) The particles of claim 1 wherein the particles further comprise a non-polymeric material.
- 10. (currently amended) Biocompatible particles for delivery of a targeting molecule to the pulmonary system wherein the targeting molecule is attached to the particles and wherein the particles have a tap density less than 0.4 g/cm-sup.3 g/cm<sup>3</sup>, and at least 90% of the particles have geometric dimensions between 5 mum µm and about 30 mum µm.
- 11. (currently amended) Biocompatible particles for delivery of a vaccine agent to the pulmonary system comprising an immunologically effective amount of a vaccine agent; wherein the particles have a tap density less than 0.4 g/cm.sup.3 g/cm³ and at least 90% of the particles have an aerodynamic diameter between about 1 .mu.m µm and about 5 .mu.m µm.
- 12. (original) The particles of claim 11 wherein the agent is selected from the group consisting of viral vaccines, bacterial vaccines, live, attenuated, recombinant, inactivated, and combinations thereof.
- 13. (currently amended) The particles of claim 11 combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 ...mu.m μm to about 100 ...mu.m μm.
- 14. (original) The particles of claim 11 combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.
- 15. (currently amended) The particles of claim 11 wherein at least 90% of the particles have an

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aerodynamic diameter between about 1 .mu.m µm and about 3 .mu.m µm.

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- 16. (currently amended) The particles of claim 11 wherein at least 90% of the particles have an aerodynamic diameter between about 3 .mu.m um and about 5 .mu.m um.
- 17. (currently amended) The particles of claim 11 wherein at least 50% of the particles have a tap density of less than 0.1 g/cm.sup.3 g/cm3.
- 18. (original) The particles of claim 11 wherein the particles further comprise a polymeric material.
- 19. (original) The particles of claim 11 wherein the particles further comprise a non-polymeric material.
- 20. (currently amended) Biocompatible particles for delivery of a vaccine and targeting molecule to the pulmonary system wherein the targeting molecule is attached to the particles and wherein the particles have a tap density less than 0.4 g/em.sup.3 g/cm³, and at least 90% of the particles have an aerodynamic diameter between about 1 mum µm and about 5 mum µm.
- 21. (currently amended) A method for delivery of an actively immunizing amount of a vaccine to the pulmonary system comprising: administering to the respiratory tract of a patient in need thereof of an effective amount of biocompatible particles incorporating said vaccine, wherein the particles have a tap density of less than about 0.4 g/cm.sup.3 g/cm<sup>3</sup> and at least 90% of the particles have geometric dimensions between about 5 .mu.m µm and about 30 .mu.m µm.
- 22. (original) The method of claim 21 wherein the agent is selected from the group consisting of viral vaccines, bacterial vaccines, live, attenuated, recombinant, inactivated, and

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combinations thereof.

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- 23. (currently amended) The method of claim 21 wherein the particles are combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 .mu.m un to about 100 .mu.m um.
- 24. (original) The method of claim 21 wherein the particles are combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.
- 25. (currently amended) The method of claim 21 wherein at least 90% of the particles have a mass mean diameter between about 5 mum µm and about 15 mum µm.
- 26. (currently amended) The method of claim 21 for delivery to the alveolar zone of the lung wherein at least 90% of the particles have a mean diameter between about 9 and about 11 .mu.m  $\mu \mathbf{m}$ .
- 27. (currently amended) The method of claim 21 wherein at least 50% of the administered particles have a tap density of less than about 0.1 g/cm.sup.3 g/cm<sup>3</sup>.
- 28. The method of claim 21 wherein the particle's further comprise a polymeric material.
- 29. (original) The method of claim 21 wherein the particles further comprise a non-polymeric material.
- 30. (currently amended) A method for delivery of a vaccine and a targeting molecule to the pulmonary system comprising; administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of biocompatible particles, wherein the particles have a tap density less than about 0.4 g/cm.sup.3 g/cm<sup>3</sup> and at least 90% of the particles

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have geometric dimensions between about 5 .mu.m um and about 30 .mu.m um, and wherein the targeting molecule is attached to the particles which further comprise the vaccine.

- 31. (currently amended) A method for delivery of a vaccine to the pulmonary system comprising: administering to the respiratory tract of a patient in need thereof of an effective amount of biocompatible particles comprising said vaccine, wherein the particles have a tap density of less than about 0.4 g/cm.sup.3 g/cm<sup>3</sup> and at least 90% of the particles have an aerodynamic diameter between about 1 .mu.m µm and about 5 .mu.m µm.
- 32. (original) The method of claim 31 wherein the agent is selected from the group consisting of viral vaccines, bacterial vaccines, live, attenuated, recombinant, inactivated, and combinations thereof.
- 33. (currently amended) The method of claim 31 wherein the particles are combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 .mu.m um to about 100 .mu.m µm.
- 34. (original) The method of claim 31 wherein the particles are combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.
- 35. (currently amended) The method of claim 31 wherein at least 90% of the particles have an aerodynamic diameter between about 1 .mu.m µm and about 3 .mu.m µm.
- 36. (currently amended) The method of claim 31 for delivery to the alveolar zone of the lung wherein at least 90% of the particles have an aerodynamic diameter between about 3 .mu.m um and about 5.mu.m µm.
- 37. (currently amended) The method of claim 31 wherein at least 50% of the administered

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particles have a tap density of less than about 0.1 g/cm.sup.3 g/cm<sup>3</sup>.

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- 38. (original) The method of claim 31 wherein the particles further comprise a polymeric material.
- 39. (original) The method of claim 31 wherein the particles further comprise a non-polymeric material.
- 40. (currently amended) A method for delivery of a vaccine and a targeting molecule to the pulmonary system comprising: administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of biocompatible particles comprising said vaccine, wherein the particles have a tap density less than about 0.4 <del>g/cm.sup.3</del> and at least 90% of the particles have an aerodynamic diameter between about 1 -mu.m μm and about 5 -mu.m μm, and wherein the targeting molecule is attached to the particles.